K040746

JUN - 8 2004

12. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Submission in accordance with the requirements of 21 CFR Part 807.87(h)

1. Submitter	: MEDIS medical imaging systems bv
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Contact Person	: J.I. Hollander, Quality Coordinator
Prepared	: March 17, 2004
2. Device Name	: MRA-CMS
Common Name	: MRA
Classification Name	: 90 LLZ (21 CFR 892.2050)
3. Predicate Device(s)	: Vital Images: 510(k) **K002519**

4. Description of the device:

MRA-CMS can be utilized to determine lumen lengths; minimum and maximum cross sectional diameters and percent stenosis. MRA-CMS improves productivity of the clinician by semi-automating the measurement function for routine vascular measurements.

5. Intended use:

MRA has been developed for the objective and reproducible analysis of MRA data
The intended purposes are:

1. Supporting clinical diagnoses about the status of the global and regional function and anatomy of the human heart;
2. Supporting the subsequent clinical decision making processes;
3. Supporting the use in clinical research trials, directed at studying changes in function and anatomy of the heart chambers as a result of treatment.

6. Substantial equivalence Information:

MRA-CMS is substantially equivalent to the Predicate Device of Vital Images, K002519 "Vitrae 2, version 2.1", using the same technological technique for the same intended use.

Conclusion respecting safety and effectiveness:

It is the opinion of Medis medical imaging systems bv that MRA-CMS is safe and potential hazards are controlled by a risk management plan for the software development process (**See Appendix C**), including hazard analysis (**See Appendix D**), verification and validation tests (**See Appendix E**). Evaluations by hospitals and literature (**See Appendix F**) support this statement. The software package MRA-CMS itself will not have any adverse effects on health. This tool calculates and displays the anatomy and function of the left and right ventricles. The ventricular contours and regions-of-interest will be interpreted by the operator, who can choose to accept or reject the outlines, and then decide to use the derived data to compare against earlier images or images from other patients.

It is the opinion of Medis medical imaging systems bv that the level of concern for the stand alone software to view images is 'minor' and that the use of MRA-CMS software does not change the intended use of MR scanners in practice, nor does the use of software result in any new potential hazards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 8 2004

Mr. J.I. Hollander
Quality Coordinator
Medis Medical Imaging Systems bv
Schuttersveld 9 2316 XG Leiden
P.O.Box 384, 2300 AJ Leiden
THE NETHERLANDS

Re: K040746
Trade/Device Name: MRA-CMS
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: March 17, 2004
Received: March 23, 2004

Dear Mr. Hollander:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K040746

Device Name: MRA-CMS

Indications For Use:

MRA-CMS has been developed for the objective and reproducible analysis of vessels from MRA data sets. The MRA software package can be used to semi-automatically calculate and display various parameters such as: lumen length, cross sectional parameters and percent stenosis. When interpreted by a trained physician these parameters may be useful in supporting the determination of a diagnosis.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

Prescription Use ✓

David A. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K040746